

CLAIMS

1. The use of an oestrogen in the manufacture of a composition containing oestrogen for the treatment of atrophic vaginitis in woman, by administering weekly an amount of about 10 to about 30 μg estradiol to a woman.
2. The use according to claim 1, wherein the women treated is menopausal or post-menopausal women.
3. The use according to any one of the preceding claims, wherein weekly an amount of about 15 to about 25 μg estradiol is administered.
4. The use according to any one of the preceding claims, wherein daily about 1.5 to about 4 μg estradiol is administered.
5. The use according to any one of the preceding claims, wherein daily about 2 to about 3 μg estradiol is administered.
6. The use according to any one of the preceding claims, wherein twice weekly about 5 to about 15 μg estradiol is administered.
7. The use according to any one of the preceding claims, wherein twice weekly about 7 to about 13 μg estradiol is administered.
8. The use according to the preceding claim, wherein twice weekly about 9 to about 11 μg estradiol is administered.
9. The use according to any one of the preceding claims, wherein no progestogen is administered.
10. The use according to any one of the preceding claims, wherein the composition is to be administered vaginally.

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11. The use according to any one of the preceding claims, wherein it is used for a period of time of more than 2 weeks, preferably more than 1 month, more preferred more than 2 months, and even more preferred more than 3 months.
12. The use according to any one of the preceding claims, wherein administration is performed using a tablet.
13. The use according to any one of the preceding claims, wherein each tablet contains, in addition to the active material, about 53.7 mg hypromellose, about 17.9 mg lactose monohydrate, about 8 mg maize starch, about 0.4 mg magnesium stearate.
14. The use according to any one of the preceding claims, wherein each tablet is coated with a film consisting of about 0.5 mg hypromellose and about 0.06 mg macrogel 6000 (polyethylene glycol 6000 NF).
15. The use according to any one of the preceding claims, furnishing no or only inferior systemic absorption.
16. The use according to any one of the preceding claims, furnishing significant improvement in the vaginal mucosa.
17. The use according to any one of the preceding claims, furnishing no or only inferior systemic effect.
18. The use according to any one of the preceding claims, furnishing low absorption of estrogen.
19. The use according to any one of the preceding claims, furnishing low serum concentration of estradiol.
20. The use according to any one of the preceding claims, furnishing no or only inferior accumulation of circulating estradiol.

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21. The use according to any one of the preceding claims, furnishing positive effects on an atrophic vaginal epithelium.
22. The use according to any one of the preceding claims, furnishing complete or substantial vaginal maturation.
23. The use according to any one of the preceding claims, furnishing a reduced risk of osteoporosis.
24. The use according to any one of the preceding claims, furnishing increases in percentage of superficial vaginal cells.
25. The use according to any one of the preceding claims, furnishing a vaginal pH value below about 5.5.
26. The use according to any one of the preceding claims, furnishing all or most of the following characteristics: Relief of vaginal symptoms, improved urogenital atrophy, decreased vaginal pH, and improved cytologic maturation of both the vaginal and urethral mucosa.
27. The use according to any one of the preceding claims, giving a clinical effect on vaginal symptoms which is as good as that obtained by administration of Vagifem® twice weekly.
28. A method of treating atrophic vaginitis, comprising administering a composition as described in any of the previous use claims.
29. A tablet comprising 17β -estradiol in an amount not more than about 15 μg , or a therapeutically equivalent amount of a salt or derivative thereof.
30. A tablet according to claim 34, wherein said tablet comprises about 53.7 mg hypromellose, about 17.9 mg lactose monohydrate, about 8 mg maize starch, and about 0.4 mg magnesium stearate.

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31. A tablet according to claim 29, wherein said amount of 17β -estradiol is in the range from about 8 to about 12 μg .

32. A tablet according to claim 31 wherein said amount of 17β -estradiol is about 10 μg .

33. Any novel feature or combination of features described herein.

34. A tablet according to claim 29, further comprising one or more of hypromellose, lactose monohydrate, maize starch, and magnesium stearate.

35. A method for treating atrophic vaginitis in a patient in need of such treatment, said method comprising administering to said patient an amount of about 10 to about 30 μg estradiol or a therapeutically equivalent amount of a salt or derivative thereof, wherein administration of said amount occurs at least once per week.

36. A method according to claim 35, wherein the patient is a menopausal or post-menopausal woman.

37. A method according to claim 35, wherein about 15 to about 25 μg estradiol or a therapeutically equivalent amount of a salt or derivative thereof is administered weekly.

38. A method according to claim 35, wherein about 1.5 to about 4 μg estradiol or a therapeutically equivalent amount of a salt or derivative thereof is administered daily.

39. A method according to claim 35, wherein about 2 to about 3 μg estradiol or a therapeutically equivalent amount of a salt or derivative thereof is administered daily.

40. A method according to claim 35, wherein about 5 to about 15 μg estradiol or a therapeutically equivalent amount of a salt or derivative thereof is administered twice weekly.

41. A method according to claim 40 wherein about 7 to about 13 μg estradiol or a therapeutically equivalent amount of a salt or derivative thereof is administered twice weekly.

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42. A method according to claim 41, wherein about 9 to about 11 μg estradiol or a therapeutically equivalent amount of a salt or derivative thereof is administered twice weekly.

43. A method according to claim 35, wherein no progestogen is administered.

44. A method according to claim 35, wherein the route of said administration is vaginally.

45. A method according to claim 35, wherein said at least once-weekly administration occurs over a period of time of more than 2 weeks

46. A method according to claim 45, wherein said period of time is more than 1 month.

47. A method according to claim 46, wherein said period of time is more than 3 months.

48. A method according to claim 35, wherein said administration is performed using a tablet.

49. A method according to claim 48, wherein each tablet comprises, in addition to estradiol or a therapeutically equivalent amount of a salt or derivative thereof, about 53.7 mg hypromellose, about 17.9 mg lactose monohydrate, about 8 mg maize starch, about 0.4 mg magnesium stearate.

50. A method according to claim 48, wherein each tablet is coated with a film consisting of about 0.5 mg hypromellose and about 0.06 mg macrogel 6000 (polyethylene glycol 6000 NF).

51. A method according to claim 48, wherein there is low or undetectable systemic absorption of said estradiol following said administration.

52. A method according to claim 35, wherein said treatment results in a vaginal pH value below about 5.5.

53. A method according to claim 35, wherein said treatment results in one or more of: Relief of vaginal symptoms, improved urogenital atrophy, decreased vaginal pH, and improved cytologic maturation of the vaginal and/or urethral mucosa.

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